

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

ROSLYN HARRIS and MARY ALLEN, on
behalf of themselves and all others similarly
situated,

Plaintiffs,

v.

PFIZER INC.,

Defendant.

Civil Action No. 1:21-cv-06789-
DLC

**FIRST AMENDED CLASS
ACTION COMPLAINT AND
DEMAND FOR JURY TRIAL**

Plaintiffs Roslyn Harris and Mary Allen (“Plaintiffs”) bring this action on behalf of themselves and all others similarly situated against Defendant Pfizer Inc. (“Pfizer” or “Defendant”). Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

NATURE OF THE ACTION

1. This is a class action lawsuit regarding Defendant’s manufacturing, distribution, and sale of varenicline-containing medications under the brand name Chantix® (“Chantix” or the “Product”) that contain dangerously high levels of N-nitroso-varenicline, a carcinogenic impurity.

2. Chantix is a prescription medication that contains the active ingredient varenicline, which is an ingredient designed to help individuals stop smoking by attaching to nicotine receptors in the brain so that nicotine cannot attach to the receptors. The varenicline still releases dopamine (much like nicotine), but to a lesser degree. This is designed to assist a person using Chantix to quit smoking by resisting the urge to smoke. However, Defendant’s

manufacturing process has caused Chantix to contain dangerously high levels of N-nitroso-varenicline, a carcinogenic impurity which was not designed to be in the medication.

3. N-nitroso-varenicline is a nitrosamine. “Nitrosamines are chemical compounds classified as probable human carcinogens on the basis of animal studies.”¹ The United States Food & Drug Administration (“FDA”) states that nitrosamines, including N-nitroso-varenicline, “are potent genotoxic agents in several animal species and some are classified as probable or possible human carcinogens by the International Agency for Research on Cancer (IARC).”² “A genotoxin is a chemical or agent that can cause DNA or chromosomal damage. . . . DNA damage in a somatic cell may result in a somatic mutation, which may lead to malignant transformation (cancer).”³

4. According to Health Canada, N-nitroso-varenicline “has been shown to cause gene mutations in an in vitro study, indicating that its presence in [Chantix] may be associated with a potential increased cancer risk in humans.”⁴ The FDA has further stated that “N-Nitroso-varenicline belongs to the nitrosamine class of compounds, some of which are classified as probable or possible human carcinogens (substances that could cause cancer), based on laboratory tests such as rodent carcinogenicity studies.”⁵

¹ <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities#:~:text=Nitrosamines%20are%20chemical%20compounds%20classified,medicines%20known%20as%20'sartans'.> (last visited 8/11/21).

² See Control of Nitrosamine Impurities in Human Drugs, at 5, available at [https://www.fda.gov/media/141720/download#:~:text=Nitrosamine%20compounds%20are%20potent%20genotoxic,Research%20on%20Cancer%20\(IARC\).](https://www.fda.gov/media/141720/download#:~:text=Nitrosamine%20compounds%20are%20potent%20genotoxic,Research%20on%20Cancer%20(IARC).) (last visited 11/1/21).

³ David H. Phillips, Genotoxicity: damage to DNA and its consequences, available at <https://pubmed.ncbi.nlm.nih.gov/19157059/> (last visited 11/1/21).

⁴ <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75961a-eng.php> (last visited 8/5/21).

⁵ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix> (last visited 8/5/21).

5. On July 2, 2021, the FDA issued an alert to patients and healthcare professionals as to Pfizer's recall of nine lots of Chantix to the warehouse level due to the presence of "a nitrosamine impurity, called N-nitroso-varenicline, above FDA's acceptable intake limit."⁶ "FDA has determined the recalled varenicline poses an unnecessary risk to patients. Therefore, FDA recommends health care professionals consider other available treatment options for the patient's medical condition."⁷ The FDA further noted that "[w]e know impurities in medicines are of great concern to patients and consumers who rely on safe and effective medicines approved by FDA."⁸

6. Later, on July 16, 2021, the FDA announced that to "ensure patient access to varenicline, FDA will not object to certain manufacturers temporarily distributing varenicline tablets containing N-nitroso-varenicline above FDA's acceptable intake limit of 37 ng per day but below the interim acceptable intake limit of 185 ng per day until the impurity can be eliminated or reduced to acceptable levels."⁹ Stated another way, medications containing more than 37 ng of N-nitroso-varenicline are not acceptable in the medication under ordinary circumstances, but because of fear of shortage, the FDA has created interim limits for presence of N-nitroso-varenicline. However, the recalled batches of Defendant's Chantix that are the subject of this action contained levels of N-nitroso-varenicline even above the FDA's interim limits, rendering them unsafe for use and unmerchantable as sold.

7. On July 19, 2021, Pfizer expanded its recall to twelve lots of Chantix "due to the

⁶ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix> (last visited 8/5/21).

⁷ *Id.*

⁸ *Id.*

⁹ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix> (last visited 8/10/21).

presence of N-nitroso-varenicline above the company's acceptable limit for this impurity.”¹⁰

8. Each of the twelve recalled lots were identified by NDC number, as well as other product identifiers:

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
Chantix (varenicline) Tablets, 0.5 mg	0069-0468-56	00019213	2022 JAN	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 0.5 mg	0069-0468-56	EC6994	2023 MAY	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 1 mg	0069-0469-56	EA6080	2023 MAR	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 1 mg	0069-0469-56	EC9843	2023 MAR	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	00020231	2021 SEP	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline)	0069-0471-03	00020232	2021 NOV	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack

¹⁰ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix> (last visited 8/10/21).

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
Tablets, 0.5/1 mg					containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471- 03	00020357	2021 DEC	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471- 03	00020358	2022 JAN	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471- 03	00020716	2022 JAN	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471- 03	ET1600	01/2023	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471- 03	ET1607	01/2023	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	ET1609	01/2023	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets

9. In connection with the recall, Pfizer instructed its wholesalers and distributors “with an existing inventory of the lots, listed in the table above, [to] stop use and distribution and quarantine the product immediately.”¹¹ Pfizer made this instruction to its wholesalers and distributors because it knew the Product was carcinogenic, unsafe, unfit for its intended use, and unmerchantable as sold.

10. The recall notice advised that consumers, like Plaintiffs and members of the Class and the New York and New Jersey Subclasses (as defined below), should consult with their health care provider and return the product subject to the recall.¹² In other words, consumers were to stop using the recalled product and return it because it was unsafe for use.

11. Later, on September 16, 2021, Pfizer expanded the recall once again to “all lots of Chantix 0.5 mg and 1 mg Tablets to the patient (consumer/user) level **due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit.**”¹³ (Emphasis added). The FDA instructed that “[w]holesalers and Distributors with an existing

¹¹ <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-issues-voluntary-nationwide-recall-twelve-lots-chantixr-varenicline-tablets-due-n-nitroso> (last visited 8/10/21).

¹² *Id.*

¹³ <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n> (last visited 11/1/21).

inventory of Chantix tablets, should stop use and distribution and quarantine the product immediately.”¹⁴ Pfizer provided additional product identification information for the recalled products, including NDC Codes and lot numbers of affected Products.¹⁵ Pfizer also included label images of the affected Products:



¹⁴ *Id.*

¹⁵ *Id.*





12. Regardless of the packaging, each iteration of the Product contains the same representation and warranty that the Product was “Chantix” and “(varenicline) TABLETS.” But the Product’s labels are false because the Product also contained the genotoxic contaminate N-nitroso-varenicline. The Product was distributed to Plaintiffs, Class members, and members of the New York and New Jersey Subclasses in the manufacturer’s packaging such that Plaintiffs and members of the Class and New York and New Jersey Subclasses reviewed the labels at the point of purchase.

13. The Product’s labeling, in each iteration, states “ALWAYS DISPENSE WITH MEDICATION GUIDE” or “ALWAYS DISPENSE WITH ENCLOSED MEDICATION GUIDE.” When Plaintiffs and class members filled their Chantix prescriptions, they received and reviewed the medication guide contained therewith. The medication guide contained similar representations and warranties regarding the Product.¹⁶ Notably, the medication guide expressly represents and warrants that the only active ingredient in the medication was “varenicline tartrate.”¹⁷ But that is false because the Product also included the genotoxic contaminate N-nitroso-varenicline.

14. Defendant did not disclose the presence of N-nitroso-varenicline at all on the Product’s label, in the medication guide, or otherwise. That is because N-nitroso-varenicline is not designed to be contained in the Product, and is in fact a harmful impurity contained therein. No reasonable consumer would have chosen to purchase Defendant’s Product had they known that it contained harmful levels of a carcinogenic impurity, to wit N-nitroso-varenicline.

¹⁶ <https://www.pfizermedicalinformation.com/en-us/chantix/medguide> (last visited 11/1/21).

¹⁷ *Id.*

15. Defendant had reason to know of the presence of N-nitroso-varenicline in Chantix, but nevertheless failed to disclose the presence of the same to Plaintiff or members of the Class and the New York and New Jersey Subclasses. Specifically, the presence of nitrosamines in prescription medications has been the subject of FDA scrutiny for over three years, as well as international regulators such as the European Medicines Agency (“EMA”).

16. “EU regulators first became aware of nitrosamines in medicines in mid-2018 when nitrosamine impurities, including N-nitrosodimethylamine (NDMA), were detected in blood pressure medicines known as ‘sartans’.”¹⁸ The FDA similarly began announcing nitrosamine-related recalls in mid-2018.¹⁹

17. Since that time, both the FDA and the EMA have implemented control strategies to ensure that medications entering the market and being sold to consumers are not contaminated with nitrosamines. For example, the EMA states that “[c]ompanies are required to have appropriate control strategies to prevent or limit the presence of these impurities and, where necessary, to improve their manufacturing processes.”²⁰ The EMA further admonished that “[m]arketing authorisation holders should review their manufacturing processes for all products containing chemically synthesised or biological active substances to identify and, if necessary,

¹⁸ <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities#:~:text=Nitrosamines%20are%20chemical%20compounds%20classified,medicines%20known%20as%20'sartans'>.

¹⁹ See, e.g., <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/major-pharmaceuticals-issues-voluntary-nationwide-recall-valsartan-due-potential-presence-probable> (last visited 8/11/21).

²⁰ <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities#:~:text=Nitrosamines%20are%20chemical%20compounds%20classified,medicines%20known%20as%20'sartans'>.

mitigate the risk of presence of nitrosamine impurities.”²¹

18. For its part, the FDA, in September 2020, published guidance for the industry entitled “Control of N-Nitrosamine Impurities in Human Drugs.”²² “This guidance recommends steps manufacturers of active pharmaceutical ingredients (APIs) and drug products should take to detect and prevent objectionable levels of nitrosamine impurities in pharmaceutical products.”²³

19. However, despite this guidance and the known risk of nitrosamine impurities in medications, Defendant’s Chantix medication still contained unacceptable levels of nitrosamine impurities, specifically N-nitroso-varenicline.

20. Further, in October of 2020, Health Canada sent a letter to Apotex, Inc. (the distributor of Chantix in Canada) concerning the presence of nitrosamines in drug products. Specifically, Health Canada informed Apotex that it had been informed by other global regulators “of the prences of new nitrosamine impurities in varenicline API [active pharmaceutical ingredient]: 7,8-dinitro-1,2,4,5-tetrahydro-3H-1,5-methanobenzo[d]azepin-N-nitrosamine, 1-(7,8-diamino-1,2,4,5-tetrahydro-3H-1,5-methanobenzo[o’l azepin-3-yl)-N-nitrosamine and N-nitroso varenicline.” Health Canada continued: “After a preliminary internal review conducted by Health Canada, it was concluded that there is risk for formation of these new nitrosamines impurities for all MAHs of varenicline drug products in Canada.” Thus, Defendant knew or should have known of the issue of nitrosamine contamination months before it ultimately announced the recalls of the Product.

21. Had Defendant engaged in proper testing of the Product and followed prevailing

²¹ *Id.*

²² <https://www.fda.gov/media/141720/download> (last visited 8/11/21).

²³ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix>

current Good Manufacturing Processes (“cGMP”) and industry guidance, it would have known that the Product contained unacceptable amounts of N-nitroso-varenicline. As such, Defendant’s conduct amounts to an actionable omission due to its failure to disclose the true nature of the Product to Plaintiff and members of the Class and New Jersey Subclass.

22. Because Defendant’s Product contained unsafe levels of N-nitroso-varenicline, it is economically worthless as it cannot be legally sold in the United States and is generally unfit for human consumption. Stated another way, Plaintiff and members of the Class and New Jersey Subclass paid a price premium in the amount of the full purchase price for the medication. No reasonable consumer would knowingly purchase the Product had they known that the Product contained a carcinogenic impurity, here N-nitroso-varenicline above acceptable intake limits set by the FDA. At minimum, Plaintiff and members of the Class and New Jersey Subclass paid a premium of the difference between the value of the Product as promised and warranted versus the value of the Product actually received.

23. Plaintiffs bring this action on behalf of themselves, the Class, and the New Jersey and New York Subclasses (defined below) for equitable relief and to recover damages and restitution for: (i) breach of express warranty, (ii) breach of the implied warranty of merchantability, (iii) violation of the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1 *et seq.*, (iv) unjust enrichment, (v) fraud, (vi) negligent misrepresentation/omission, (vii) violation of New York’s General Business Law § 349, and (viii) violation of New York’s General Business Law § 350.

PARTIES

A. Plaintiff Harris

24. Plaintiff Roslyn Harris is a citizen of New Jersey who resides in Jersey City, New

Jersey. On or around June 21, 2021, Plaintiff Harris purchased and filled a Chantix “Starting Month” pack containing one “Starting Week” pack of eleven 0.5 mg tablets and three “Continuing Weeks” packs of forty-two 1 mg tablets through Express Scripts in New Jersey. Plaintiff Harris purchased the Product in New Jersey and paid a co-pay for the Product. The package she purchased bore the NDC Code 0069-0471-03, which is one of the NDC Codes subject to the recall. More specifically, the package bore the Lot Number ET1600 with an expiration date of January 2023. As such, Ms. Harris purchased a now recalled lot of the Product. When Ms. Harris purchased the Product on or around June 21, 2021, she reviewed the labels and disclosures on the Product, including the representation and warranty that the Product was “Chantix” and had the active ingredient varenicline because the Product’s label represented that the Product was “(varenicline) TABLETS.” She reasonably understood this to mean that the Product would be “Chantix” as approved by the FDA, and would contain only varenicline as the active ingredient. Based on those representations and warranties, Plaintiff Harris chose to purchase the Product, relying on Defendant’s representations and warranties. But Defendant’s representations and warranties were false because the Product in fact contained a dangerous nitrosamine impurity, namely N-nitroso-varenicline, above acceptable limits set by the FDA. The Product’s labeling did not reference N-nitroso-varenicline, as the presence of the same was actively and knowingly concealed from her by Defendant, who knew or had reason to know that the Product contained harmful N-nitroso-varenicline. Plaintiff Harris suffered harm because she would not have purchased the Product on the same terms had she known that the Product was not, in fact, Chantix as approved by the FDA or that the Product actually contained dangerous nitrosamine active ingredients (N-nitroso-varenicline) above acceptable intake limits. Because the Product contained N-nitroso-varenicline above acceptable limits, it is worthless and in fact

illegal to sell in the United States because it is both adulterated and misbranded. Said another way, Plaintiff Harris paid a premium in the amount of the full purchase price of the Product. At minimum, Plaintiff Harris paid a premium measured as the difference between the Product as warranted and the Product actually received.

25. Plaintiff Harris purchased Chantix on three prior occasions. The first was on or around July 16, 2019 wherein Plaintiff Harris purchased a “Chantix Starting Month Box” bearing NDC Code 0069-0471-03 from a Rite Aid location in Jersey City, New Jersey. Plaintiff Harris paid a co-pay of \$10 for the Product. This NDC Code was also subject to recall. Plaintiff Harris purchased and consumed the Product without knowing that the Product contained a harmful impurity, N-nitroso-varenicline. When Ms. Harris purchased the Product on or around July 16, 2019, she reviewed the labels and disclosures on the Product, including the representation and warranty that the Product was “Chantix” and had the active ingredient varenicline because the Product’s label represented that the Product was “(varenicline) TABLETS.” She reasonably understood this to mean that the Product would be “Chantix” as approved by the FDA, and would contain only varenicline as the active ingredient. Based on those representations and warranties, Plaintiff Harris chose to purchase the Product, relying on Defendant’s representations and warranties. But Defendant’s representations and warranties were false because the Product in fact contained a dangerous nitrosamine impurity, namely N-nitroso-varenicline, above acceptable limits set by the FDA. The Product’s labeling did not reference N-nitroso-varenicline, as the presence of the same was actively and knowingly concealed from her by Defendant, who knew or had reason to know that the Product contained harmful N-nitroso-varenicline. Plaintiff Harris suffered harm because she would not have purchased the Product on the same terms had she known that the Product was not, in fact, Chantix as approved by the FDA

or that the Product actually contained dangerous nitrosamine active ingredients (N-nitroso-varenicline) above acceptable intake limits. Because the Product contained N-nitroso-varenicline above acceptable limits, it is worthless and in fact illegal to sell in the United States because it is both adulterated and misbranded. Said another way, Plaintiff Harris paid a premium in the amount of the full purchase price of the Product. At minimum, Plaintiff Harris paid a premium measured as the difference between the Product as warranted and the Product actually received.

26. On or around August 21, 2019, Plaintiff Harris purchased a Chantix 1 mg Continuing Month Box bearing NDC Code 0069-0469-03 from a Rite Aid location in Jersey City, New Jersey. Plaintiff Harris paid a co-pay of \$30 for the Product. This NDC Code was also subject to recall. Plaintiff Harris purchased and consumed the Product without knowing that the Product contained a harmful impurity, N-nitroso-varenicline. When Ms. Harris purchased the Product on or around July 16, 2019, she reviewed the labels and disclosures on the Product, including the representation and warranty that the Product was “Chantix” and had the active ingredient varenicline because the Product’s label represented that the Product was “(varenicline) TABLETS.” She reasonably understood this to mean that the Product would be “Chantix” as approved by the FDA, and would contain only varenicline as the active ingredient. Based on those representations and warranties, Plaintiff Harris chose to purchase the Product, relying on Defendant’s representations and warranties. But Defendant’s representations and warranties were false because the Product in fact contained a dangerous nitrosamine impurity, namely N-nitroso-varenicline, above acceptable limits set by the FDA. The Product’s labeling did not reference N-nitroso-varenicline, as the presence of the same was actively and knowingly concealed from her by Defendant, who knew or had reason to know that the Product contained

harmful N-nitroso-varenicline. Plaintiff Harris suffered harm because she would not have purchased the Product on the same terms had she known that the Product was not, in fact, Chantix as approved by the FDA or that the Product actually contained dangerous nitrosamine active ingredients (N-nitroso-varenicline) above acceptable intake limits. Because the Product contained N-nitroso-varenicline above acceptable limits, it is worthless and in fact illegal to sell in the United States because it is both adulterated and misbranded. Said another way, Plaintiff Harris paid a premium in the amount of the full purchase price of the Product. At minimum, Plaintiff Harris paid a premium measured as the difference between the Product as warranted and the Product actually received.

27. Finally, on or around February 17, 2021, Plaintiff Harris purchased a Chantix Starting Month Box bearing NDC Code 0069-0471-03 from a Rite Aid location in Jersey City, New Jersey. Plaintiff Harris paid a co-pay of \$20 for the Product. This NDC Code was also subject to recall. Plaintiff Harris purchased and consumed the Product without knowing that the Product contained a harmful impurity, N-nitroso-varenicline. When Ms. Harris purchased the Product on or around July 16, 2019, she reviewed the labels and disclosures on the Product, including the representation and warranty that the Product was “Chantix” and had the active ingredient varenicline because the Product’s label represented that the Product was “(varenicline) TABLETS.” She reasonably understood this to mean that the Product would be “Chantix” as approved by the FDA, and would contain only varenicline as the active ingredient. Based on those representations and warranties, Plaintiff Harris chose to purchase the Product, relying on Defendant’s representations and warranties. But Defendant’s representations and warranties were false because the Product in fact contained a dangerous nitrosamine impurity, namely N-nitroso-varenicline, above acceptable limits set by the FDA. The Product’s labeling did not

reference N-nitroso-varenicline, as the presence of the same was actively and knowingly concealed from her by Defendant, who knew or had reason to know that the Product contained harmful N-nitroso-varenicline. Plaintiff Harris suffered harm because she would not have purchased the Product on the same terms had she known that the Product was not, in fact, Chantix as approved by the FDA or that the Product actually contained dangerous nitrosamine active ingredients (N-nitroso-varenicline) above acceptable intake limits. Because the Product contained N-nitroso-varenicline above acceptable limits, it is worthless and in fact illegal to sell in the United States because it is both adulterated and misbranded. Said another way, Plaintiff Harris paid a premium in the amount of the full purchase price of the Product. At minimum, Plaintiff Harris paid a premium measured as the difference between the Product as warranted and the Product actually received.

28. In choosing to purchase her Chantix medication from Defendant, Ms. Harris reviewed the accompanying labels and disclosures described herein, and understood them as representations and warranties by the manufacturer that the Product was properly manufactured, free from defects, and safe for its intended use. Ms. Harris relied on these representations and warranties in deciding to purchase Chantix from Defendant, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased Chantix from Defendant on the same terms if she had known that it was not, in fact, properly manufactured and free from defects. Ms. Harris also understood that each purchase involved a direct transaction between herself and Pfizer because her medication came with packaging and other materials prepared by Pfizer, including representations and warranties described herein.

29. On or around July 21, 2021, Plaintiff Harris received an “Urgent Product Recall” letter from Rite Aid, which stated that “Pfizer is voluntarily recalling the [Product] due [to] the

presence of N-nitroso-varenicline above the . . . Acceptable Daily Intake (ADI) level.” The letter further advised that “[t]he affected lots of Chantix were distributed nationwide to Rite Aid and McKesson distributor customers starting June, 2019.” The letter continued: “You are receiving this letter because we have filled one or more prescriptions for you using the Chantix implicated above since June 2019.” Thus, it is clear from the Rite Aid letter that each of Plaintiff Harris’ fills of the Product were affected by the recall.

30. To date, Plaintiff Harris has not received a refund for the defective Chantix medications she purchased, nor would a simple refund be adequate as she and class members are entitled to, among other things, trebled damages under the NJCFA, punitive damages, and recovery of attorneys’ fees and costs. Further, Plaintiff Harris seeks relief not only on her own behalf, but on behalf of a class of similarly-situated consumers.

B. Plaintiff Allen

31. Plaintiff Mary Allen is a citizen of New York who resides in Warrensburg, New York. On or around April 16, 2020, Plaintiff Allen purchased and filled a Chantix “Continuing Month Box” of 56 1 mg tablets from a Walgreens location in Warrensburg, New York. The package bore the NDC Code 0069-0469-03, Lot Number 00022176, and expiration date of September 2022. This Product was subject to the recall. As such, Plaintiff Allen purchased a now recalled Product. Plaintiff Allen paid a co-pay for the medication. When Ms. Allen purchased the Product on or around April 16, 2020, she reviewed the labels and disclosures on the Product, including the representation and warranty that the Product was “Chantix” and had the active ingredient varenicline because the Product’s label represented that the Product was “(varenicline) TABLETS.” She reasonably understood this to mean that the Product would be “Chantix” as approved by the FDA, and would contain only varenicline as the active ingredient.

Based on those representations and warranties, Plaintiff Harris chose to purchase the Product, relying on Defendant's representations and warranties. But Defendant's representations and warranties were false because the Product in fact contained a dangerous nitrosamine impurity, namely N-nitroso-varenicline, above acceptable limits set by the FDA. The Product's labeling did not reference N-nitroso-varenicline, as the presence of the same was actively and knowingly concealed from her by Defendant, who knew or had reason to know that the Product contained harmful N-nitroso-varenicline. Plaintiff Allen suffered harm because she would not have purchased the Product on the same terms had she known that the Product was not, in fact, Chantix as approved by the FDA or that the Product actually contained dangerous nitrosamine active ingredients (N-nitroso-varenicline) above acceptable intake limits. Because the Product contained N-nitroso-varenicline above acceptable limits, it is worthless and in fact illegal to sell in the United States because it is both adulterated and misbranded. Said another way, Plaintiff Allen paid a premium in the amount of the full purchase price of the Product. At minimum, Plaintiff Allen paid a premium measured as the difference between the Product as warranted and the Product actually received.

32. On or around May 12, 2020, Plaintiff Allen purchased and filled a Chantix "Continuing Month Box" of 56 1 mg tablets from a Walgreens location in Warrensburg, New York. The package bore the NDC Code 0069-0469-03, Lot Number 00022176, and expiration date of September 2022. This Product was subject to the recall. As such, Plaintiff Allen purchased a now recalled Product. Ms. Allen paid a co-pay for the medication. When Ms. Allen purchased the Product on or around April 16, 2020, she reviewed the labels and disclosures on the Product, including the representation and warranty that the Product was "Chantix" and had the active ingredient varenicline because the Product's label represented that the Product was

“(varenicline) TABLETS.” She reasonably understood this to mean that the Product would be “Chantix” as approved by the FDA, and would contain only varenicline as the active ingredient. Based on those representations and warranties, Plaintiff Harris chose to purchase the Product, relying on Defendant’s representations and warranties. But Defendant’s representations and warranties were false because the Product in fact contained a dangerous nitrosamine impurity, namely N-nitroso-varenicline, above acceptable limits set by the FDA. The Product’s labeling did not reference N-nitroso-varenicline, as the presence of the same was actively and knowingly concealed from her by Defendant, who knew or had reason to know that the Product contained harmful N-nitroso-varenicline. Plaintiff Allen suffered harm because she would not have purchased the Product on the same terms had she known that the Product was not, in fact, Chantix as approved by the FDA or that the Product actually contained dangerous nitrosamine active ingredients (N-nitroso-varenicline) above acceptable intake limits. Because the Product contained N-nitroso-varenicline above acceptable limits, it is worthless and in fact illegal to sell in the United States because it is both adulterated and misbranded. Said another way, Plaintiff Allen paid a premium in the amount of the full purchase price of the Product. At minimum, Plaintiff Allen paid a premium measured as the difference between the Product as warranted and the Product actually received.

33. On or around June 21, 2021, Plaintiff Allen purchased, filled, and partially consumed a Chantix Starting Month Box of eleven 0.5 mg tablets and three “Continuing Weeks” packs of forty-two 1 mg tablets from 201 Warrensburg Housecalls Pharmacy in Warrensburg, New York. The package she purchased bore the NDC Code 0069-0471-03, which is one of the NDC Codes subject to the recall. More specifically, the package bore the Lot Number ET1611 and Expiration Date January 2023. As such, Ms. Allen purchased a now recalled Product. Ms.

Allen paid a co-pay of \$3 for the Product. When Ms. Allen purchased the Product on or around June 21, 2021, she reviewed the labels and disclosures on the Product, including the representation and warranty that the Product was “Chantix” and had the active ingredient varenicline because the Product’s label represented that the Product was “(varenicline) TABLETS.” She reasonably understood this to mean that the Product would be “Chantix” as approved by the FDA, and would contain only varenicline as the active ingredient. Based on those representations and warranties, Plaintiff Allen chose to purchase the Product, relying on Defendant’s representations and warranties. But Defendant’s representations and warranties were false because the Product in fact contained a dangerous nitrosamine impurity, namely N-nitroso-varenicline, above acceptable limits set by the FDA. The Product’s labeling did not reference N-nitroso-varenicline, as the presence of the same was actively and knowingly concealed from her by Defendant, who knew or had reason to know that the Product contained harmful N-nitroso-varenicline. Plaintiff Allen suffered harm because she would not have purchased the Product on the same terms had she known that the Product was not, in fact, Chantix as approved by the FDA or that the Product actually contained dangerous nitrosamine active ingredients (N-nitroso-varenicline) above acceptable intake limits. Because the Product contained N-nitroso-varenicline above acceptable limits, it is worthless and in fact illegal to sell in the United States because it is both adulterated and misbranded. Said another way, Plaintiff Allen paid a premium in the amount of the full purchase price of the Product. At minimum, Plaintiff Allen paid a premium measured as the difference between the Product as warranted and the Product actually received.

34. To date, Plaintiff Allen has not received a refund for the defective Chantix medications she purchased, nor would a simple refund be adequate as she and class members are

entitled to statutory damages under New York's consumer-protection laws, punitive damages, and recovery of attorneys' fees and costs. Further, Plaintiff Allen seeks relief not only on her own behalf, but on behalf of a class of similarly-situated consumers.

C. Defendant Pfizer

35. Defendant Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017. At all relevant times, Pfizer manufactured and distributed Chantix throughout the United States, and specifically in the States of New York and New Jersey. At all relevant times, Pfizer was in control of, and responsible for, the manufacturing, testing, marketing, labeling and general oversight of the Product and sales of the same in the United States. Pfizer conducts substantial business in the United States, and specifically in the States of New York and New Jersey.

JURISDICTION AND VENUE

36. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds \$5,000,000 exclusive of interest and costs.

37. This Court has personal jurisdiction over Defendant because Defendant is incorporated and maintains its principal place of business in New York, and is therefore subject to general jurisdiction in New York.

38. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendant has its principal place of business in this District.

FACTS COMMON TO ALL CLAIMS

39. Plaintiffs hereby expressly incorporate by reference all of the facts set forth in the Nature of the Action section.

40. In 2005, Defendant submitted a New Drug Application for Chantix, NDA 21-928.²⁴ Chantix was approved by the FDA on May 10, 2006. However, the Product, as approved by the FDA, was not designed to contain nitrosamines, and specifically was not designed to contain N-nitroso-varenicline.

41. “For decades, the regulation and control of new drugs in the United States has been based on the New Drug Application (NDA). Since 1938, every new drug has been the subject of an approved NDA before U.S. commercialization. The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.”²⁵

42. Further, “[t]he documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, **what the ingredients of the drug are**, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged.”²⁶ In short, every aspect of the drug, including its ingredients and labeling, must conform to the NDA.

43. In turn, consumers like Plaintiffs and Class members expect that when they receive a medication, including Chantix, that they will receive the drug as approved by the FDA. But that is not what Plaintiffs and Class members received in this case. Instead, they received a

²⁴ https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021928_s000_Chantix_Approv.pdf (last visited 11/2/21).

²⁵ <https://www.fda.gov/drugs/types-applications/new-drug-application-nda> (last visited 11/2/21).

²⁶ *Id.*

drug containing N-nitroso-varenicline, which is not an approved ingredient in Chantix as approved by the FDA. Therefore, Plaintiffs and class members received something other than “Chantix” as approved by the FDA, and by representing the Product as “Chantix” and the only active ingredient as varenicline, Defendant breached an express warranty and made an affirmative false representation to Plaintiffs and class members.

44. Each of the Chantix medications sold to Plaintiffs and Class members contained N-nitroso-varenicline above acceptable daily intake limits prescribed by the FDA. Defendant admitted as much in its recall notice, recalling “all lots of Chantix 0.5 mg and 1 mg Tablets to the patient (consumer/user) level **due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit.**”²⁷ (Emphasis added). As such, the Products were unmerchantable as sold because it is unlawful to sell medication containing nitrosamines above the acceptable daily intake limit set by the FDA.

45. The Products were additionally unmerchantable because, as sold, they were both adulterated and misbranded under federal and New Jersey law, and therefore illegal to sell. Notably, Plaintiffs are not seeking to enforce the federal Food, Drug and Cosmetic Act (“FDCA”); rather, that the Products fall below the quality standard and are illegal to sell under federal law demonstrates that they are unmerchantable and unfit for their intended purpose.

46. The Product is adulterated because “it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.” 21 U.S.C. § 351(b); *see also* 21 U.S.C. § 351(c) (“If it is not subject to the provisions of paragraph (b) of this section

²⁷ <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n> (last visited 11/1/21).

and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.”); 21 U.S.C. § 351(a) (a drug is adulterated “if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess”). New Jersey law integrates several of the same prohibitions. *See* N.J. Stat. Ann. § 24:5-10(b) (a drug is adulterated “[i]f it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below the standard set forth in such compendium”); N.J. Stat. Ann. § 24:5-10(c) (“If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below that which it purports or is represented to possess.”); N.J. Stat. Ann. § 24:5-10(e) (“If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.”). The Product is adulterated because Defendant failed to comply with cGMPs in manufacturing the Product, leading to its contamination, and because it contains N-nitroso-varenicline above acceptable daily limits. Therefore, the Product’s “purity or quality falls below[] that which it purports or is represented to possess.” It is also dangerous to health because of the presence of the nitrosamine impurity.

47. A drug product is misbranded if “its labeling is false or misleading in any particular.” 21 U.S.C. § 352(a)(1); N.J. Stat. Ann. § 24:5-16 (“The term ‘misbranded’ as used in this subtitle shall apply to all drugs, articles of food, cosmetics and devices and to articles which enter into the composition of foods, drugs, cosmetics or devices, the package or label of which

shall bear any statement or design regarding such article or the ingredients or substances contained therein, which shall be false or misleading in any particular . . .”). The Products are misbranded because they are advertised as “Chantix” when in fact they contain N-nitroso-varenicline. The Products are also misbranded because they purport to contain only the active ingredient varenicline but in fact contain N-nitroso-varenicline.

48. Both adulterated and misbranded drugs are illegal to sell. 21 U.S.C. § 331; N.J. Stat. Ann. § 24:5-1 (“No person shall distribute or sell, or manufacture for distribution or sale, or have in his possession with intent to distribute or sell, any food, drug, cosmetic or device which under any of the provisions of this subtitle is adulterated or misbranded.”).

49. Defendant engaged in extensive marketing to advertise Chantix to consumers, including television commercials.²⁸

CLASS ALLEGATIONS

50. Plaintiffs seek to represent a class defined as all persons in the United States who purchased Chantix (the “Class”). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendant, Defendant’s officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant’s officers and/or directors, the judge assigned to this action, and any member of the judge’s immediate family.

51. Plaintiff Harris also seeks to represent a subclass of all Class members who

²⁸ <https://www.youtube.com/watch?v=1oVH1dRgHYY> (last visited 11/2/21); https://www.youtube.com/watch?v=s3F21_ncTg4 (last visited 11/2/21).

purchased Chantix in New Jersey (the “New Jersey Subclass”).

52. Plaintiff Allen also seeks to represent a subclass of all Class members who purchased Chantix in New York (the “New York Subclass”).

53. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class and New Jersey Subclass may be expanded or narrowed by amended complaint or at class certification.

54. **Numerosity.** The members of the Class and the New York and New Jersey Subclasses are geographically dispersed throughout the United States and the States of New York and New Jersey and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiffs reasonably estimate that there are hundreds of thousands of members in the Class and tens of thousands of members in both the New Jersey and New York Subclasses. Although the precise number of Class and New York and New Jersey Subclass members is unknown to Plaintiff, the true number of Class and New York and New Jersey Subclass members is known by Defendant and/or third-party retailers and may be determined through discovery. Class, New York Subclass and New Jersey Subclass members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

55. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and New York and New Jersey Subclasses and predominate over any questions affecting only individual Class and New York and New Jersey Subclass members. These common legal and factual questions include, but are not limited to, the following:

- (a) whether the Chantix medication manufactured by Defendant contains dangerously

high levels of N-nitroso-varenicline, thereby breaching the express and implied warranties made by Defendant and making Chantix unfit for human consumption and therefore unfit for its intended purpose;

(b) whether Defendant knew or should have known that Chantix contained elevated levels of N-nitroso-varenicline prior to selling the medication, thereby constituting fraud and/or fraudulent concealment;

(c) whether Defendant is liable to Plaintiffs and the Class and New York and New Jersey Subclasses for unjust enrichment;

(e) whether Defendant is liable to Plaintiffs and the Class and New York and New Jersey Subclasses for fraud;

(f) whether Defendant is liable to Plaintiff Harris and the New Jersey Subclass for violations of New Jersey's consumer-protection laws, and liable to Plaintiff Allen and the New York Subclass for violation of New York's consumer-protection laws;

(g) whether Plaintiffs and the Class and New York and New Jersey Subclasses have sustained monetary loss and the proper measure of that loss;

(h) whether Plaintiffs and the Class and the New York and New Jersey Subclasses are entitled to declaratory and injunctive relief;

(i) whether Plaintiffs and the Class and the New York and New Jersey Subclasses are entitled to restitution and disgorgement from Defendant; and

(j) whether the marketing, advertising, packaging, labeling, and other promotional materials for Chantix are deceptive.

56. **Typicality.** Plaintiffs' claims are typical of the claims of the other members of the Class and the New York and New Jersey Subclasses in that Defendant mass marketed and

sold defective Chantix to consumers throughout the United States. By definition, this defect was present in all of the Chantix manufactured by Defendant. Therefore, Defendant breached its express and implied warranties to Plaintiffs and the Class and the New York and New Jersey Subclass members by manufacturing, distributing, and selling the defective Chantix. Plaintiffs' claims are typical in that they and the Class were uniformly harmed in purchasing and consuming the defective Chantix. Plaintiffs' claims are further typical in that Defendant deceived Plaintiffs in the very same manner as it deceived each member of the Class and the New York and New Jersey Subclasses. Further, there are no defenses available to Defendant that are unique to Plaintiffs.

57. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Class and the New York and New Jersey Subclasses. Plaintiffs have retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiffs intend to vigorously prosecute this action on behalf of the Class and the New York and New Jersey Subclasses. Furthermore, Plaintiffs have no interests that are antagonistic to those of the Class and the New York and New Jersey Subclasses.

58. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class and New York and New Jersey Subclass members are relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for the Class and the New York and New Jersey Subclasses, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class and New York and New Jersey Subclass members could afford such individualized litigation, the court system could not. Individualized litigation would create the

danger of inconsistent or contradictory judgments arising from the same set of facts.

Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

59. In the alternative, the Class and the New York and New Jersey Subclasses may also be certified because:

(a) the prosecution of separate actions by individual Class and New York and New Jersey Subclass members would create a risk of inconsistent or varying adjudications with respect to individual Class and New York and New Jersey Subclass members that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual Class and New York and New Jersey Subclass members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class and New York and New Jersey Subclass members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendant has acted or refused to act on grounds generally applicable to the Class and New York and New Jersey Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and New Jersey Subclass as a whole.

COUNT I
Breach Of Express Warranty
(On Behalf Of Plaintiffs, The Class, And The New York and New Jersey Subclasses)

60. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

61. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and the New York and New Jersey Subclasses against Defendant.

62. Plaintiffs, and each member of the Class and the New York and New Jersey Subclasses, formed a contract with Defendant at the time Plaintiffs and the other Class and New York and New Jersey Subclass members purchased the defective Chantix. The terms of the contract include the promises and affirmations of fact made by Defendant on the Product's packaging and through marketing and advertising, including that the Product would be "Chantix" as approved by the FDA, and would contain only the active ingredient stated on the label (varenicline), and not harmful impurities such as N-nitroso-varenicline.

63. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and the New York and New Jersey Subclasses and Defendant.

64. Plaintiffs relied on the express warranty that the Product would be "Chantix" as approved by the FDA, and would contain only the active ingredient stated on the label (varenicline), and not harmful impurities such as N-nitroso-varenicline. These express warranties further formed the basis of the bargain, and is part of the standardized contract between Plaintiffs and the members of the Class and the New York and New Jersey Subclasses and Defendant.

65. Defendant purports, through its advertising, labeling, marketing and packaging, to create an express warranty that the Product would be “Chantix” as approved by the FDA, and would contain only the active ingredient stated on the label (varenicline), and not harmful impurities such as N-nitroso-varenicline.

66. Plaintiffs and the Class and the New York and New Jersey Subclasses performed all conditions precedent to Defendant’s liability under this contract when they purchased the defective medication.

67. Defendant breached express warranties about the defective Chantix and its qualities because Defendant’s statements about the defective Chantix were false because the defective Chantix Plaintiffs and members of the Class and New Jersey Subclass purchased do not conform to Defendant’s affirmations and promises described above.

68. Plaintiffs and each of the members of the Class and the New York and New Jersey Subclasses would not have purchased the defective Chantix on the same terms had they known the true nature of the defective Chantix’s composition, specifically that Chantix contained elevated levels of N-nitroso-varenicline and was not, in fact, “Chantix” as approved by the FDA.

69. As a result of Defendant’s breach of express warranty, Plaintiffs and each of the members of the Class and the New York and New Jersey Subclasses have been damaged in the amount of the purchase price of Chantix, or at minimum the difference between the value of the Product as promised and warranted versus the value of the Product actually received, and any consequential damages resulting from the purchases.

70. On August 11, 2021, prior to filing this action, Plaintiff Harris served Defendant with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiffs’ counsel sent Defendant a letter advising Defendant that it breached an express warranty and

demanded that it cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiffs' counsel's letter is attached hereto as **Exhibit A**.

71. On November 1, 2021, prior to filing the First Amended Complaint, Plaintiff Allen served Defendant with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiffs' counsel sent Defendant a letter advising Defendant that it breached an express warranty and demanded that it cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiffs' counsel's letter is attached hereto as **Exhibit B**.

COUNT II
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of Plaintiffs, The Class, And The New York and New Jersey Subclasses)

72. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

73. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and the New York and New Jersey Subclasses against Defendant.

74. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that Chantix (i) would not contain elevated levels of N-nitroso-varenicline above acceptable daily intake limits, (ii) is generally recognized as safe for human consumption, and (iii) was not adulterated or misbranded such that the Product was lawful to sell in the United States and in the States of New York and New Jersey. By selling the defective Product to Plaintiffs and Class members and members of the New York and New Jersey Subclasses, Defendant breached each of these implied warranties.

75. Defendant breached the warranty implied in the contract for the sale of the

defective Chantix because it could not pass without objection in the trade under the contract description, the Chantix was not of fair or average quality within the description, and the Chantix was unfit for its intended and ordinary purpose because the Chantix manufactured by Defendant was defective in that it contained elevated levels of carcinogenic N-nitroso-varenicline above the legal limit, and as such is not generally recognized as safe for human consumption. As a result, Plaintiffs and Class and New Jersey Subclass members did not receive the goods as impliedly warranted by Defendant to be merchantable.

76. Plaintiffs, Class, and New York and New Jersey Subclass members purchased Chantix in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

77. The Chantix medication purchased by Plaintiffs and members of the Class and the New York and New Jersey Subclasses was not altered by Plaintiffs or Class or New York and New Jersey Subclass members.

78. The Chantix was defective when it left the exclusive control of Defendant.

79. Defendant knew that the Chantix medication would be purchased and used without additional testing by Plaintiffs and the Class and the New York and New Jersey Subclass members.

80. The Chantix medications that Plaintiffs, the Class, and the New York and New Jersey Subclasses purchased were defectively manufactured and unfit for their intended purpose because they contained elevated levels of N-nitroso-varenicline above the legal limit, and Plaintiff and Class and New Jersey Subclass members did not receive the goods as warranted. The Product was also adulterated and misbranded, and as such was unfit for use as a prescription medication because adulterated and misbranded medications are illegal to sell.

81. As a direct and proximate cause of Defendant's breach of the implied warranty, Plaintiffs and Class and New York and New Jersey Subclass members have been injured and harmed because: (a) they would not have purchased Chantix on the same terms if they knew that Chantix contained harmful levels of N-nitroso-varenicline, and is not generally recognized as safe for human consumption; and (b) Chantix does not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

82. On August 11, 2021, prior to filing this action, Plaintiff Harris served Defendant with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-314, 2-607. Plaintiffs' counsel sent Defendant a letter advising Defendant that it breached an implied warranty and demanded that it cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiffs' counsel's letter is attached hereto as **Exhibit A**.

83. On November 1, 2021, prior to filing the First Amended Complaint, Plaintiff Allen served Defendant with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiffs' counsel sent Defendant a letter advising Defendant that it breached an implied warranty and demanded that it cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiffs' counsel's letter is attached hereto as **Exhibit B**.

COUNT III
Violation Of New Jersey's Consumer Fraud Act
(On Behalf Of Plaintiff Harris And The New Jersey Subclass)

84. Plaintiff Harris hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

85. Plaintiff Harris brings this claim individually and on behalf of the members of the

proposed New Jersey Subclass against Defendant.

86. The New Jersey Consumer Fraud Act (“NJCFA”) prohibits “[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice... .” N.J.S.A. § 56:8-2.

87. Plaintiff Harris and members of the New Jersey Subclass are consumers who purchased Chantix for personal, family, or household use.

88. Plaintiff Harris and New Jersey Subclass members suffered an injury in fact and lost money or property as a result of Defendant’s violations of the NJCFA.

89. In violation of the NJCFA, Defendant employed unconscionable commercial practices, deception, fraud, and/or false pretense by manufacturing and selling Chantix that is contaminated with N-nitroso-varenicline and presents a safety risk to consumers and users of Chantix. Defendant misrepresented and/or engaged in deceptive conduct by stating to Plaintiff and members of the New Jersey Subclass that the Chantix they purchased was “Chantix” as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline.

90. Defendant’s deception was material in that it induced Plaintiff and members of the New Jersey Subclass to purchase the Product under false pretenses, namely that the Product

was fit for human use and not contaminated. Plaintiff and New Jersey Subclass members reviewed the labels, advertising, and/or marketing of Defendant's Product, reasonably acted in positive response to those representations and were thereby deceived. Plaintiffs would not have purchased Defendant's Product on the same terms but for Defendant's material misrepresentations. Plaintiffs and members of the Class who purchased Defendant's Product were overcharged for these products, which by law were worthless. At minimum, Plaintiff and members of the New Jersey Subclass paid a considerable price premium for the Product.

91. Additionally, Defendant knowingly failed to disclose and concealed the contamination of the defective Chantix with the intent that Plaintiff and members of the New Jersey Subclass rely on said concealment, in violation of the NJCFA. Defendant's fraudulent omissions were material to Plaintiff and members of the New Jersey Subclass. When Plaintiff and members of the New Jersey Subclass purchased Chantix, they reasonably relied on the expectation that Chantix (i) would not contain dangerously high levels of N-nitroso-varenicline, and (ii) was generally recognized as safe for human consumption. Had Defendant disclosed that Chantix contained dangerously high levels of N-nitroso-varenicline and was unsafe for human consumption, Plaintiff and members of the New Jersey Subclass would not have purchased Chantix or would they have paid less for it.

92. Defendant knowingly concealed, suppressed and/or omitted the presence of the N-nitroso-varenicline contamination and safety risk in Chantix at the time of sale and at all relevant times thereafter. If Defendant followed cGMPs and industry standards as described herein, and adequately tested the Product, it would have known of the nitrosamine contamination.

93. Defendant owed a duty to disclose the N-nitroso-varenicline contamination and its

corresponding safety risk to Plaintiff and members of the New Jersey Subclass because Defendant possessed superior and exclusive knowledge regarding the N-nitroso-varenicline contamination and the risks associated with the consumption of N-nitroso-varenicline.

94. Defendant knew, or should have known, that the N-nitroso-varenicline contamination in Chantix made Chantix unsafe for human consumption. As discussed herein, both the FDA and international regulators have imposed more stringent testing requirements for nitrosamine contamination, which if followed would have revealed the presence of N-nitroso-varenicline.

95. As a direct and proximate result of Defendant's wrongful conduct in violation of the NJCFA, Plaintiff and members of the New Jersey Subclass have suffered and continue to suffer ascertainable loss in the form of the purchase price paid for defective, worthless Chantix medications. At minimum, Plaintiffs paid a premium price for the Products. The amount of the price premium can be reasonably quantified by an appropriate market study, through contingent variation study, or through other means regularly employed by economic and valuation experts.

96. On behalf of herself and other members of the New Jersey Subclass, Plaintiff Harris seeks to recover actual damages, treble damages, costs, attorneys' fees, and other damages to be determined at trial. *See* N.J.S.A. § 56:8-19.

97. On August 11, 2021, prior to filing this action, Defendant was served with a pre-suit notice letter advising Defendant of its violation of the NJCFA and demanding full restitution. A true and correct copy of Plaintiff's counsel's letter is attached hereto as **Exhibit A**.

98. In accordance with N.J.S.A. § 56:8-20, a copy of this complaint will be sent to the Attorney General within ten (10) days of filing the same.

COUNT IV

Unjust Enrichment

(On Behalf Of Plaintiffs, The Class, And The New York and New Jersey Subclasses)

99. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

100. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and the New York and New Jersey Subclasses against Defendant.

101. Plaintiffs and the Class and the New York and New Jersey Subclasses conferred a benefit on Defendant in the form of monies paid to purchase Defendant's defective Chantix medications.

102. Defendant voluntarily accepted and retained this benefit.

103. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications unfit for human use, it would be unjust and inequitable for the Defendant to retain it without paying the value thereof.

COUNT V

Fraud

(On Behalf Of Plaintiffs, The Class, and The New York and New Jersey Subclasses)

104. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

105. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and the New York and New Jersey Subclasses against Defendant.

106. As discussed above, Defendant provided Plaintiffs, the Class and the New York and New Jersey Subclass members with materially false or misleading information about the Chantix manufactured by Defendant. Specifically, Defendant affirmatively represented on the Product's packaging and labeling that the Product was "Chantix" as approved by the FDA when

in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline.

107. Defendant marketed Chantix as safe for human consumption, and further represented that the Chantix medications purchased and used by Plaintiffs and the Class and the New York and New Jersey Subclasses would contain only the ingredients stated on the label, and not harmful carcinogens such as N-nitroso-varenicline. As indicated above, however, these representations are false and misleading as Defendant's Chantix medications contained elevated levels of N-nitroso-varenicline which rendered them unfit for use.

108. Defendant also engaged in material omissions by concealing from Plaintiffs and Class members and members of the New York and New Jersey Subclasses the presence of the harmful carcinogen N-nitroso-varenicline in the Product.

109. Defendant's material misrepresentations and omissions occurred at the point of sale.

110. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiffs and Class and New York and New Jersey Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiffs and Class and New York and New Jersey Subclass members to purchase defective Chantix.

111. Defendant knew or reasonably should have known that Chantix was contaminated with this harmful impurity, but continued to manufacture it nonetheless. As discussed herein, both the FDA and international regulators have imposed more stringent testing requirements for nitrosamine contamination, which if followed would have revealed the presence of N-nitroso-varenicline. If Defendant followed cGMPs and industry standards as described herein, and adequately tested the Product, it would have known of the nitrosamine contamination.

112. The fraudulent actions of Defendant caused damage to Plaintiff and Class and New Jersey Subclass members, who are entitled to damages and other legal and equitable relief as a result.

113. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT VI
Negligent Misrepresentation/Omission
(On Behalf Of Plaintiffs, The Class, and The New York and New Jersey Subclasses)

114. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

115. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and the New York and New Jersey Subclasses against Defendant.

116. In representing that the Product was "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline, Defendant negligently provided false information to Plaintiff and Class members and members of the New York and New Jersey Subclasses.

117. Plaintiffs and Class members were reasonably foreseeable recipients of the false information promulgated by Defendant because Plaintiffs and Class members and members of the New York and New Jersey Subclasses were the intended purchasers of the Products. Defendant's labels were designed to advertise the Product to consumers like Plaintiffs and Class members.

118. Plaintiffs and Class and New York and New Jersey Subclass members justifiably relied on the false information promulgated by Defendant because they reasonably believed that

the Product was, in fact, “Chantix” as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline. Plaintiffs and Class members and members of the New York and New Jersey Subclasses purchased the Product based on Defendant’s false representations regarding the Product. Had Plaintiff and Class members known the truth about the Products, they would not have purchased the Products on the same terms.

119. The damages asserted by Plaintiffs and Class members and members of the New York and New Jersey Subclasses were proximately caused by the false statements because Plaintiffs and Class members and members of the New York and New Jersey Subclasses reviewed the Products’ labeling and representations, specifically the claims that the Product was “Chantix” as approved by the FDA and that the Product would contain only the active ingredients stated on the label, and chose to purchase the Products based on those false representations.

120. Plaintiffs and Class members and members of the New York and New Jersey Subclasses are entitled to damages and other legal and equitable relief as a result of Defendant’s conduct.

COUNT VII
Violation of New York G.B.L. § 349
(On Behalf of Plaintiff Allen and the New York Subclass)

121. Plaintiff Allen hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

122. Plaintiff Allen brings this claim individually and on behalf of the New York Subclass against Defendant.

123. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

124. In its sale of goods throughout the State of New York, Defendant conducts business and trade within the meaning and intendment of New York's General Business Law § 349.

125. Plaintiff Allen and members of the New York Subclass are consumers who purchased the Product from Defendant for their personal use.

126. By the acts and conduct alleged herein, Defendant has engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the Product was "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline.

127. The foregoing deceptive acts and practices were directed at consumers. As set forth above, Chantix is a smoking cessation drug that Defendant advertised directly to consumers through advertising and commercials. Chantix is an optional drug for individuals who wish to have assistance quitting smoking, and are able to make a purchasing decision as to whether or not to use Chantix, in addition to consultation with a medical professional. As such, Defendant's conduct is consumer-oriented.

128. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the Products to induce consumers to purchase the same. By representing the Product as "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-

varenicline, Defendant not only misled Plaintiff but also misled a significant portion of the general consuming public and/or of targeted consumers acting reasonably under the circumstances.

129. By reason of this conduct, Defendant engaged in deceptive conduct in violation of New York's General Business Law.

130. Defendant's actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff and members of the New York Subclass have sustained from having paid for and used Defendant's Products.

131. As a result of Defendant's violations, Plaintiff and members of the Class have suffered damages because the Product as sold was worthless (Plaintiff Allen and the New York Subclass paid a price premium in the amount of the full purchase price of the medication) because it was contaminated with N-nitroso-varenicline and was illegal to sell in the United States. At minimum, Plaintiff Allen and members of the New York Subclass paid a price premium for the Products based on the materially misleading representation that the Product was "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline.

132. On behalf of herself and other members of the Class, Plaintiff seeks to recover her actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT VIII
Violation of New York G.B.L. § 350
(On Behalf of Plaintiff Allen and the New York Subclass)

133. Plaintiff Allen hereby incorporates by reference the allegations contained in all

preceding paragraphs of this complaint.

134. Plaintiff Allen brings this claim individually and on behalf of the New York Subclass against Defendant.

135. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

136. Based on the foregoing, Defendant has engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of the New York General Business Law.

137. The foregoing advertising was directed at consumers and was likely to mislead a reasonable consumer acting reasonably under the circumstances.

138. These misrepresentations have resulted in consumer injury or harm to the public interest.

139. Based on the foregoing, Defendant has engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 by misrepresenting the Product as "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline. By representing the Product as "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline, Defendant not only misled Plaintiff but also misled a significant portion of the general consuming public and/or of targeted consumers acting reasonably under the circumstances.

140. The foregoing advertising was directed at consumers and was likely to mislead a

reasonable consumer acting reasonably under the circumstances.

141. As set forth above, Chantix is a smoking cessation drug that Defendant advertised directly to consumers through advertising and commercials. Chantix is an optional drug for individuals who wish to have assistance quitting smoking, and are able to make a purchasing decision as to whether or not to use Chantix, in addition to consultation with a medical professional. As such, Defendant's conduct is consumer-oriented.

142. This misrepresentation has resulted in consumer injury or harm to the public interest.

143. As a result of Defendant's violations, Plaintiff and members of the New York Subclass have suffered damages because they paid a price premium in the amount of the full purchase price for the Products based on the materially misleading representation that the Products were "Chantix" as approved by the FDA when in fact it was not, and that the Product would contain only the active ingredients stated on the label, when in fact it contained harmful, carcinogenic impurities such as N-nitroso-varenicline. At minimum, Plaintiff Allen and members of the New York Subclass paid a price premium in the amount of the difference between the Product as represented and warranted and the Product actually received.

144. On behalf of herself and the members of the New York Subclass, Plaintiff seeks to enjoin the unlawful acts and practices described herein, to recover actual damages or five hundred dollars per violation, whichever is greater, three times actual damages and reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seek judgment against Defendant, as follows:

- A. For an order certifying the nationwide Class and the New York and New Jersey Subclasses under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as the representative for the Class and the New York and New Jersey Subclasses and Plaintiffs' attorneys as Class Counsel;
- B. For an order declaring the Defendant's conduct violates the statutes referenced herein;
- C. For an order finding in favor of Plaintiffs, the Class, the New Jersey Subclass and the New York Subclass on all counts asserted herein;
- D. For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;
- E. For prejudgment interest on all amounts awarded;
- F. For an order of restitution and all other forms of equitable monetary relief; and
- G. For an order awarding Plaintiffs and the Class and the New York and New Jersey Subclasses their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of any and all issues in this action so triable of right.

Dated: November 10, 2021

Respectfully submitted,

BURSOR & FISHER, P.A.

By: /s/ Andrew J. Obergfell
Andrew J. Obergfell

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EXHIBIT A



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ANDREW J. OBERGFELL
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aobergfell@bursor.com

August 11, 2021

Via Federal Express

Pfizer Inc.
235 East 42nd Street
New York, NY 10017

*Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607;
New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-1, et seq.;
And all other relevant state and local laws*

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Pfizer Inc. (“Pfizer”) pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties – and violations of state consumer protection laws – related to our client, Roslyn Harris, and a class of all similarly situated purchasers (the “Class”) of contaminated Chantix® (“Chantix” or the “Product”) medication manufactured by Pfizer.

Our client was prescribed and purchased Chantix, a medication containing the active-ingredient varenicline, manufactured by Pfizer. Our client’s Chantix was defective in that it contained elevated levels of N-nitroso-varenicline, a carcinogenic impurity. On July 2, 2021, the FDA issued an alert to patients and healthcare professionals as to Pfizer’s recall of nine lots of Chantix to the warehouse level due to the presence of “a nitrosamine impurity, called N-nitroso-varenicline, above FDA’s acceptable intake limit.”¹ On July 19, 2021, Pfizer expanded its recall to twelve lots of Chantix “due to the presence of N-nitroso-varenicline above the company’s acceptable limit for this impurity.”² This defect rendered the Product unusable and unfit for human consumption. In short, the Chantix medications that our client and the Class purchased are worthless, as they contain N-nitroso-varenicline, rendering them unusable and unfit for human consumption. Pfizer violated express and implied warranties made to our client and the Class regarding the quality and safety of the Chantix they purchased. *See* U.C.C. §§ 2-313, 2-314. Pfizer represented to Plaintiff and Class members that the Chantix medication they purchased would only contain the ingredients stated on the label, and not unnamed harmful carcinogens, to wit N-nitroso-varenicline. Further, because the Chantix medication purchased by our client and Class members was contaminated and recalled, the Product was unmerchantable as sold.

¹ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix> (last visited 8/5/21).

² <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix> (last visited 8/10/21).

Additionally, this letter also serves as notice of violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-1 *et seq.* (“NJCF”), and all other relevant state and local laws. As a result of Pfizer’s violation of the NJCFA, Ms. Harris sustained injury.

On behalf of our client and the Class, we hereby demand that Pfizer immediately make full restitution to all purchasers of the defective Chantix of all purchase money obtained from sales thereof.

We also demand that Pfizer preserve all documents and other evidence which refers or relates to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the packaging, labeling, and manufacturing process for Pfizer’s Chantix;
2. All documents concerning the design, development, supply, production, extraction, and/or testing of Chantix;
3. All nitrosamine testing of Chantix;
4. All documents concerning the pricing, advertising, marketing, and/or sale of Chantix;
5. All communications with customers involving complaints or comments concerning Chantix;
6. All documents concerning communications with any retailer involved in the marketing or sale of Chantix;
7. All documents concerning communications with federal, state or international regulators; and
8. All documents concerning the total revenue derived from sales of Chantix.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Andrew J. Obergfell

Andrew J. Obergfell

EXHIBIT B



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ANDREW J. OBERGFELL
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Fax: 212.989.9163
aobergfell@bursor.com

November 1, 2021

Via Federal Express

Pfizer Inc.
235 East 42nd Street
New York, NY 10017
c/o DLA Piper LLP (US)

*Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607;
And all other relevant state and local laws*

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Pfizer Inc. (“Pfizer”) pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties – and violations of state consumer protection laws – related to our client, Mary Allen, and a class of all similarly situated purchasers (the “Class”) of contaminated Chantix® (“Chantix” or the “Product”) medication manufactured by Pfizer.

Our client was prescribed and purchased Chantix, a medication containing the active-ingredient varenicline, manufactured by Pfizer. Our client’s Chantix was defective in that it contained elevated levels of N-nitroso-varenicline, a carcinogenic impurity. On July 2, 2021, the FDA issued an alert to patients and healthcare professionals as to Pfizer’s recall of nine lots of Chantix to the warehouse level due to the presence of “a nitrosamine impurity, called N-nitroso-varenicline, above FDA’s acceptable intake limit.”¹ On July 19, 2021, Pfizer expanded its recall to twelve lots of Chantix “due to the presence of N-nitroso-varenicline above the company’s acceptable limit for this impurity.”² On September 16, 2021, Pfizer expanded the recall once again to “all lots of Chantix 0.5 mg and 1 mg Tablets to the patient (consumer/user) level due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit.” This defect rendered the Product unusable and unfit for human consumption. In short, the Chantix medications that our client and the Class purchased are worthless, as they contain N-nitroso-varenicline, rendering them unusable and unfit for human consumption. Pfizer violated express and implied warranties made to our client and the Class regarding the quality and safety of the Chantix they purchased. *See* U.C.C. §§ 2-313, 2-314. Pfizer represented to Plaintiff and Class members that the Chantix medication they purchased would only contain the ingredients stated on the label, and not unnamed harmful carcinogens, to wit N-nitroso-

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varenicline. Further, because the Chantix medication purchased by our client and Class members was contaminated and recalled, the Product was unmerchantable as sold.

On behalf of our client and the Class, we hereby demand that Pfizer immediately make full restitution to all purchasers of the defective Chantix of all purchase money obtained from sales thereof.

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2. All documents concerning the design, development, supply, production, extraction, and/or testing of Chantix;
3. All nitrosamine testing of Chantix;
4. All documents concerning the pricing, advertising, marketing, and/or sale of Chantix;
5. All communications with customers involving complaints or comments concerning Chantix;
6. All documents concerning communications with any retailer involved in the marketing or sale of Chantix;
7. All documents concerning communications with federal, state or international regulators; and
8. All documents concerning the total revenue derived from sales of Chantix.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Andrew J. Obergfell

Andrew J. Obergfell